Patented Medicine Prices Review Board

2008-2009

Report on Plans and Priorities

The Honourable Tony Clement
Minister of Health and the Minister for the Federal Economic Development Initiative for Northern Ontario

Table of Contents

SECTION I – OVERVIEW 1

Chairperson's Message 3

Management Representation Statement 5

Raison d'être 6

Organizational Information 6
Health Portfolio 6
The Patented Medicine Prices Review Board 6

Program Activity Architecture (PAA) Crosswalk 8

Voted and Statutory Items displayed in the Main Estimates 8

Planned Spending and Full-time Equivalents 9

Summary Information 10

PMPRB Priorities 10

Program Activities by Strategic Outcome 10

PMPRB Plans and Priorities 11
Priority 1: Compliance and enforcement of non-excessive pricing for patented medicines 11
Priority 2: Pharmaceutical trends 12

SECTION II – ANALYSIS OF PROGRAM ACTIVITY BY STRATEGIC OUTCOME ... 15

Analysis by Program Activity 17
Strategic Outcome 17
Program Activity 1: Compliance and Enforcement of non-excessive prices for patented medicines 17
Program Activity 2: Pharmaceutical trends 20

SECTION III – SUPPLEMENTARY INFORMATION 23

Table 1: Departmental links to the Government of Canada Outcomes 25

SECTION I – OVERVIEW

Chairperson's Message

I am pleased to present the 2008-2009 Report on Plans and Priorities for the Patented Medicine Prices Review Board (PMPRB).

The PMPRB is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act*. Its mandate is two-fold: Regulatory – to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care; and, Reporting – to report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees thereby contributing to informed decisions and policy-making. The PMPRB contributes to the broader objective of improving the health of Canadians by reducing excessive patented drug prices and related cost pressures on the health care system.

From its creation, the PMPRB has been largely able to carry out its mandate with limited recourse to public hearings. This fact is not a sign of any reluctance on the part of the PMPRB to apply the law, but rather a measure of the success of the Board's Excessive Price Guidelines (Guidelines) and its Voluntary Compliance Policy. In 2005-2006, the PMPRB identified a risk under its regulatory mandate stemming largely from an unprecedented number of investigations and anticipated hearings into excessive drug prices and the need to update and modernize Board's Guidelines. The PMPRB received incremental funding of $5M in each of 2006-2007 and 2007-2008, through the Estimates process, to address these needs and pressures. The PMPRB's capacity to carry out its statutory mandate is focused on its ability to conduct hearings, when needed, and ensure its Guidelines are relevant and effective. Hearings of the PMPRB have increased in number and complexity in recent years. A total of 9 hearings have been initiated since January 2006. This compares to 8 hearings in total in the period from 1987 to 2005.

The current Guidelines date from 1994. Initiatives such as, the *Transparent Drug System for Patients Act, 2006,* in Ontario, amendments to the *Act respecting prescription drug insurance and other legislative provisions*, in Quebec (2005), and the federal/provincial/territorial National Pharmaceuticals Strategy, have brought renewed attention to drug prices and cost trends. At the same time, the PMPRB has heard concerns from many of its stakeholders about high introductory drug prices and other issues. To respond to these concerns, the Board initiated a process to review its Guidelines, including consulting with key stakeholders as required by the *Patent Act*. As a result of their response, significant analytical work and face-to-face consultations were held. Further work on potential options for changing the Guidelines, along with bilateral consultations with industry, governments and consumers are taking place, with a view to completing the Guidelines review in the fall of 2008. In addition, a Federal Court of Canada decision in March 2007 has raised other concerns that the current *Patented Medicines Regulations, 1994* (Regulations) and Guidelines may create disincentives for patentees to offer various benefits to customers. The PMPRB is now also assessing further options to address these concerns. Once decisions are taken and implemented, ongoing monitoring and adjustments will be undertaken, as needed, to ensure the Guidelines remain appropriate and effective in the context of the modern pharmaceutical environment, and that the price review process continues to be transparent and predictable.

At the direction of the Minister of Health in 2001, the PMPRB is also working in collaboration with the Canadian Institute for Health Information (CIHI) and participating federal/provincial/territorial drug plans to produce analyses and reports under the National Prescription Drug Utilization Information System (NPDUIS). Through critical analyses of price, utilization and cost trends, the PMPRB provides Canada's health system with more comprehensive, timely and accurate information on prescription drug trends and cost drivers.

In the context of the National Pharmaceuticals Strategy, in October of 2005, the PMPRB received direction from the federal Minister of Health to monitor and report on non-patented prescription drug prices. Beginning in 2008-2009, this work will be folded under the broader umbrella of NPDUIS.

The PMPRB remains committed to fairness and transparency in the fulfilment of its mandate.

Brien G. Benoit, MD
Chairperson

Management Representation Statement

I submit for tabling in Parliament, the 2008-2009 Report on Plans and Priorities (RPP) for the Patented Medicine Prices Review Board.

This document has been prepared based on the reporting principles contained in the *Guide for the Preparation of Part III of the 2008-09 Estimates: Reports on Plans and Priorities and Departmental Performance Reports*:

- It adheres to the specific reporting requirements outlined in the Treasury Board of Canada Secretariat guidance;
- It is based on the department's strategic outcome and program activities that were approved by the Treasury Board;
- It presents consistent, comprehensive, balanced and reliable information;
- It provides a basis of accountability for the results achieved with the resources and authorities entrusted to it; and
- It reports finances based on approved planned spending numbers from the Treasury Board of Canada Secretariat.

Brien G. Benoit, MD
Chairperson

Raison d'être

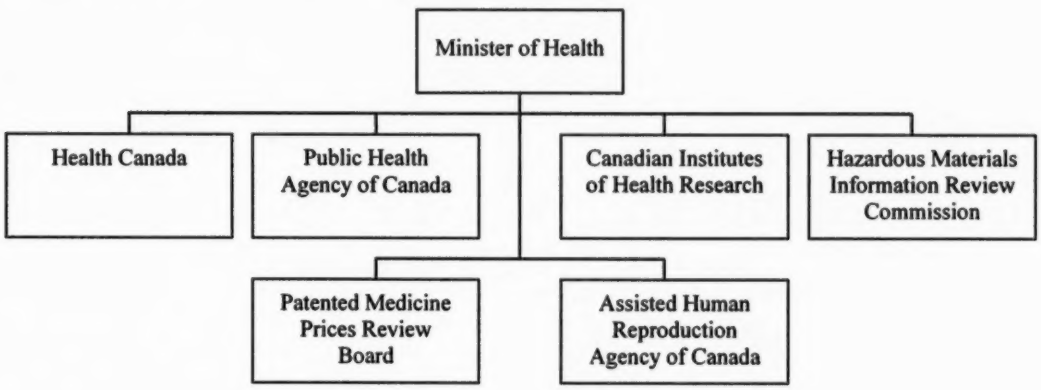
The Patented Medicine Prices Review Board (PMPRB) has a dual role:

> **Regulatory** – To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.
>
> **Reporting** – To report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy-making.

Organizational Information

Health Portfolio

The Minister of Health is responsible for maintaining and improving the health of Canadians. This is supported by the Health Portfolio which comprises Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, the Hazardous Materials Information Review Commission, the Patented Medicine Prices Review Board and Assisted Human Reproduction Canada. Each member of the Portfolio prepares its own Report on Plans and Priorities. The Health Portfolio consists of approximately 12,000 full-time equivalent employees and an annual budget of over $3.8 billion.


Minister of Health
Health Canada
Public Health Agency of Canada
Canadian Institutes of Health Research
Hazardous Materials Information Review Commission
Patented Medicine Prices Review Board
Assisted Human Reproduction Agency of Canada

The Patented Medicine Prices Review Board

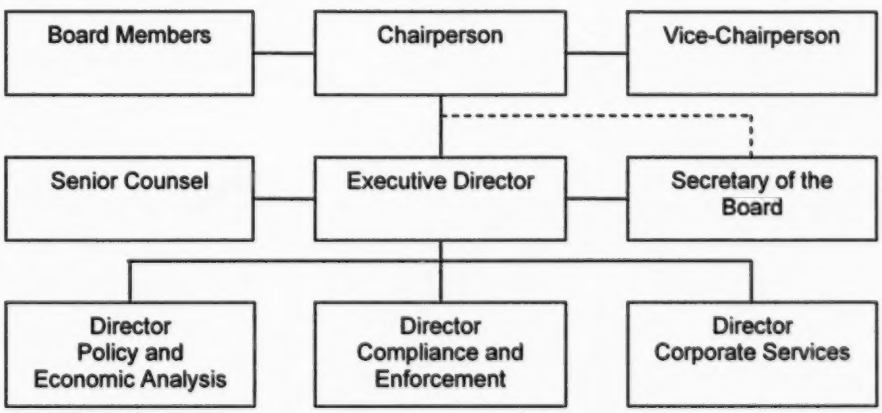
The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* as set out in sections 79 to 103. The Minister's responsibilities include tabling reports in Parliament on the activities of the PMPRB: the Report on Plans and Priorities, the Departmental Performance Report and the PMPRB Annual Report as required by the *Patent Act*. The Minister also recommends to the Governor-in-Council the appointment of Board Members and changes to the

Patented Medicines Regulations, 1994 (Regulations). He/she may also request the Board to conduct inquiries under section 90 of the *Patent Act*.

The Board consists of not more than five members who serve on a part-time basis, appointed by the Governor-in-Council, including a Chairperson and Vice-Chairperson. In June 2006, the Vice-Chairperson, Dr. Benoit, was appointed as Chairperson and Mary Catherine Lindberg was appointed Member and Vice-Chairperson for a 5 year term. Anne Warner LaForest was appointed Member of the Board in March 2007 for a 5 year term. Anthony Boardman was appointed for a second term as Member in 2005 and Thomas (Tim) Armstrong was appointed for a second term in 2007.

The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB with the authority and responsibility to supervise and direct its work. The Executive Director manages the work of the staff. Senior staff consists of the Executive Director, the Director of Compliance and Enforcement, the Director of Policy and Economic Analysis, the Director of Corporate Services, the Secretary of the Board, and Senior Counsel.

The Compliance and Enforcement Branch is responsible for the review of patented medicine prices and implementing the Compliance and Enforcement Policy. The Policy and Economic Analysis Branch is largely responsible for conducting policy analyses, providing policy advice, and preparing reports on price trends and other economic studies. The Secretariat of the Board, Corporate Services and Legal Services provide Board communications, administrative and legal support, respectively. The Secretary also provides support to the Board Members and manages the hearing process.



Program Activity Architecture (PAA) Crosswalk

2008-2009			
New Program Activities			
($ thousands)	**Compliance and enforcement of non-excessive pricing for patented medicines**	**Pharmaceutical trends**	**Total**
Patented Medicine Prices Review	3,194.0	2,648.0	5,842.0

This change in the Program Activity Architecture separates the PMPRB's program into the two distinct roles identified in the *Patent Act*, namely regulatory and reporting.

Voted and Statutory Items displayed in the Main Estimates

($ thousands)

Vote or Statutory Item	Truncated Vote or Statutory Wording	**2008-2009 Main Estimates**	2007-2008 Main Estimates
35	Operating expenditures	**5,211.0**	10,584.0
(S)	Contributions to employee benefit plans	**631.0**	891.0
	Total PMPRB	**5,842.0**	11,475.0

The reduction in the Main Estimates for 2008-2009 is due to: 1) the termination of additional funding in the amount of $5 million received through the Main Estimates in 2007-2008 to conduct public hearings and modernize the Excessive Price Guidelines; 2) a new Memorandum of Agreement between the PMPRB and Health Canada to fund the PMPRB's work under the National Prescription Drug Utilization Information System (NPDUIS) that reduces funding from $1.350 million to $850 thousand (separate funding for NPPDP reporting remained unchanged at $560 thousand and is now also folded under the NPDUIS umbrella); and 3) a reduction of $200 thousand in funding received to enhance its price review process through Health Canada's Therapeutic Access Strategy (TAS).

Planned Spending and Full-time Equivalents

($ thousands)	Forecast Spending 2007-2008	Planned Spending 2008-2009	Planned Spending 2009-2010	Planned Spending 2010-2011
Patented Medicine Prices Review	11,475.0	-	-	-
Compliance and enforcement of non-excessive pricing for patented medicines	-	3,194.0	3,194.0	3,194.0
Pharmaceutical trends	-	2,648.0	2,648.0	2,648.0
Budgetary Main Estimates (gross)	11,475.0	5,842.0	5,842.0	5,842.0
Less: Respendable revenue	-	-	-	-
Total Main Estimates	**11,475.0**	**5,842.0**	**5,842.0**	**5,842.0**
Adjustments:				
Procurement Savings				
Compliance and enforcement of non-excessive pricing for patented medicines	-	-	-	-
Pharmaceutical trends	-	-	-	-
Other				
Treasury Board Vote 15	42.0			
Employee Benefit Plan (EBP)	8.0			
Total Adjustments	50.0			
Total Planned Spending	**11,525.0**	**5,842.0**	**5,842.0**	**5,842.0**
Less: Non-respendable revenue[1]	(9,478.5)	-	-	-
Plus: Cost of services received without charge[2]	981.4	835.5	824.0	824.4
Total PMPRB Spending	**3,027.9**	**6,677.5**	**6,666.0**	**6,666.4**
Full-time Equivalents	**62.0**	**46.0**	**46.0**	**46.0**

1 The money reported as non-respendable revenue does not represent revenues generated by the PMPRB. This money is a result of payments made by patentees to the Government of Canada through Voluntary Compliance Undertakings (VCUs) or Board Orders to offset excess revenues. The Minister may enter into agreements with any province or territory respecting the distribution to provinces and territories of amounts received by the Receiver General from recovered excess revenues, less any costs incurred in relation to the collection and distribution of those amounts.

2 Services provided without charge are for: accommodation provided by Public Works and Government Services Canada; contributions covering employer's share of employees' insurance premiums and expenditures paid by the Treasury Board of Canada Secretariat; and Salary and associated expenditures of legal services provided by the Department of Justice Canada.

Summary Information

Financial Resources ($ thousands)

2008-2009	2009-2010	2010-2011
5,842.0	5,842.0	5,842.0

Human Resources

2008-2009	2009-2010	2010-2011
46.0	46.0	46.0

PMPRB Priorities

Name	Type
1. Compliance and enforcement of non-excessive pricing for patented medicines	Ongoing
2. Pharmaceutical trends	Ongoing

Program Activities by Strategic Outcome

		Planned Spending ($ thousands)			
	Expected Results	2008-2009	2009-2010	2010-2011	Contributes to the following priority
Strategic Outcome:	Canadians and their health care system are protected from excessive pricing for patented medicines sold in Canada and are informed on pharmaceutical trends.				
Program Activity 1: Compliance and enforcement of non-excessive pricing for patented medicines	Prices charged by patentees for patented medicines in Canada are not excessive according to the factors of the *Patent Act*.	3,194.0	3,194.0	3,194.0	Priority 1
Program Activity 2: Pharmaceutical trends	Stakeholders are more aware of pharmaceutical trends and cost drivers.	2,648.0	2,648.0	2,648.0	Priority 2

PMPRB Plans and Priorities

Priority 1: Compliance and enforcement of non-excessive pricing for patented medicines

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body created by Parliament as a result of revisions to the *Patent Act* in 1987 (Bill C-22) which increased patent term protection for pharmaceuticals. The PMPRB represents the strategic component of the federal government's patent policy to protect consumers and contribute to affordable health care in view of other measures designed to protect intellectual property.

The PMPRB is responsible for ensuring that the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies, or others, for human and veterinary use, are not excessive.[3]

Board Staff reviews the prices of all patented medicines sold in Canada to ensure that they are within the Board's Excessive Price Guidelines (Guidelines).[4] When it finds that the price of a patented drug product appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will conduct an investigation to determine if the price of the patented medicine in fact exceeds the Guidelines.[5] An investigation could result in:

- its closure, where it is concluded that the price was within the Guidelines;
- a Voluntary Compliance Undertaking (VCU) by the patentee to reduce the price and take measures to comply with the Guidelines including the repayment of excess revenues obtained as a result of excessive prices; or
- a recommendation to the Chairperson that it is in the public interest to hold a public hearing to determine if the price is excessive and, if so, for the Board to make a remedial order.

The PMPRB's capacity to carry out its statutory mandate is focused on its ability to conduct hearings, as needed, and ensure its Guidelines are relevant and effective. Hearings of the PMPRB have increased in number and complexity in recent years. A total of 9 hearings have been initiated since January 2006. This compares to 8 hearings in total in the period from 1987 to 2005. Pressure on the PMPRB's capacity to carry out its statutory mandate is expected to continue for the foreseeable future.

---

[3] The PMPRB has no authority to regulate the prices of non-patented drugs, and does not have jurisdiction over prices charged by wholesalers or retailers, or over pharmacists' professional fees. Also, matters such as whether medicines are reimbursed by public drug plans and prescribing are outside the purview of the PMPRB.

[4] Additional information on the Guidelines can be found in Chapter 1 of the *Compendium of Guidelines, Policies and Procedures* which is available on the PMPRB Web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

[5] Additional information on the criteria for commencing an investigation can be found in Schedule 5 of the *Compendium of Guidelines, Policies and Procedures* which is available on the PMPRB Web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

The PMPRB initiated a dialogue with stakeholders (industry, federal/provincial/territorial governments, and consumers, as required by the *Patent Act*, and others) beginning with its *Price Increases for Patented Medicines: Discussion Paper*, in 2005. In May 2006, the PMPRB released a second *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines* focused on introductory price matters. As a result of the response from stakeholders, significant analytical work was done and face-to-face stakeholder consultation meetings were held in the fall of 2006. Further work on potential options for changing the Guidelines, along with bilateral consultations with industry, governments and consumers took place in 2007.

An additional issue surfaced in 2007, when the Federal Court of Canada (FCC) issued a ruling in response to a judicial review application, that the Regulations required patentees to include all benefits in the calculation of the Average Price of a patented medicine. Patentees have stated that this will be a disincentive for the provision of benefits to customers, or may result in the discontinuation of current benefits, as the inclusion of benefits would drive down the Average Price.

The PMPRB continues to make progress on the issues under the general review of the Guidelines. In addition, the PMPRB is legally obligated to abide by the Regulations and the decisions of the Federal Court, and is therefore considering potential changes to both the Regulations and the Guidelines that are consistent with its statutory responsibility to ensure that the prices of patented medicines sold in Canada are not excessive, but at the same time not unduly create disincentives relative to benefits for customers.

Work also continued on the development of proposed amendments to the *Patented Medicines Regulations, 1994* (Regulations) which prescribe what information will be filed to the Board as well as the deadlines for doing so. The original proposed amendments to the Regulations were published in the *Canada Gazette*, Part I on December 31, 2005. Since then, stakeholder comments were analyzed and further revisions were made. As a result of this consultation, a need for broader consultation was identified and the proposed amendments to the Regulations were published again in the *Canada Gazette,* Part I on October 6, 2007. Following final publication in the *Canada Gazette*, Part II, expected early in the new fiscal year, the Regulations will come into force on the day they are registered unless a later implementation date for certain provisions is specified. At that time, Board Staff will advise patentees of all changes to the filing requirements and will provide revised forms to ensure appropriate implementation of all amendments to the Regulations, as well as initiate educational outreach activities.

In fiscal year 2007-2008, through the Main Estimates, the PMPRB received additional financial resources to conduct public hearings and modernize the Guidelines. This temporary funding sunsets at the end of 2007-2008 as reflected in the Financial Tables on pages 8 and 9 of this report. The PMPRB is currently seeking approval to revise its permanent funding to reflect ongoing pressures and operational needs.

Priority 2: Pharmaceutical trends

The PMPRB reports annually to Parliament through the Minister of Health, as required by section 100 of the *Patent Act*. The PMPRB's Annual Report, which covers the calendar year, includes: a review of its major activities; analyses of prices of patented medicines and price

trends of all drugs; and R&D expenditures as reported by patentees. The PMPRB also reports through its quarterly NEWSletter and various studies on both its activities and pharmaceutical trends.

In addition, pursuant to an agreement by the federal/provincial/territorial (F/P/T) Ministers of Health, and at the request of the federal Minister of Health, under section 90 of the *Patent Act*, the PMPRB conducts research under the National Prescription Drug Utilization Information System (NPDUIS). The purpose of the PMPRB's role in the NPDUIS, a partnership initiative with the Canadian Institute for Health Information (CIHI), is to provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost increases.

In October 2005, the Federal Minister of Health, on behalf of himself and his P/T colleagues, directed the PMPRB to monitor and report on the prices of non-patented prescription drugs in Canada in the context of the National Pharmaceuticals Strategy. Beginning in 2008-2009, this reporting will folded into PMPRB's broader studies under NPDUIS.

Funding for initiatives undertaken at the direction of the Minister is provided, pursuant to a Memorandum of Agreement, through ongoing reallocations from Health Canada's budget.

SECTION II – ANALYSIS OF PROGRAM ACTIVITY BY STRATEGIC OUTCOME

Analysis by Program Activity

The PMPRB has one strategic outcome and two program activities.

Strategic Outcome

Canadians and their health care system are protected from excessive pricing for patented medicines sold in Canada and are informed on pharmaceutical trends.

Program Activities:

1: Compliance and enforcement of non-excessive prices for patented medicines.

2: Pharmaceutical Trends.

Program Activity 1: Compliance and enforcement of non-excessive prices for patented medicines

Financial Resources ($ thousands)

2008-2009	2009-2010	2010-2011
3,194.0	3,194.0	3,194.0

Human Resources

2008-2009	2009-2010	2010-2011
25.5	25.5	25.5

The PMPRB is responsible for ensuring that the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented drugs sold in Canada to wholesalers, hospitals, pharmacies, or others, for human and veterinary use, are not excessive.

The PMPRB relies on voluntary compliance wherever possible since it is more effective, less time consuming, and less costly to all parties. Voluntary compliance by patentees is facilitated by published Guidelines which are intended to assist patentees in setting prices that are not excessive by providing transparent and predictable information on how the price review will be carried out. The Guidelines are published in the PMPRB's *Compendium of Guidelines, Policies and Procedures* (Compendium) and are available on the Web site: www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

The PMPRB reviews introductory and ongoing pricing information, as filed semi-annually pursuant to the *Patented Medicines Regulations, 1994*, for all patented medicines sold in Canada to ensure that they are not excessive.

The Guidelines provide a means of operationalizing the price determination factors in section 85 of the *Patent Act* and have been developed and modified in consultation with stakeholders, including the pharmaceutical industry, federal, provincial and territorial Ministers of Health, and consumer groups (pursuant to subsection 96(5) of the *Patent Act*), and other stakeholders as determined by the Board.

Section 85 of the *Patent Act* states:

85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

a) the price at which the medicine has been sold in the relevant market;

b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

d) changes in the Consumer Price Index (CPI); and

e) such other factors as may be specified in any regulations made for the purposes of this subsection.

85. (2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

a) the cost of making and marketing the medicines; and

b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

85. (3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

The Guidelines set out how these factors will be assessed. They set out three categories for new medicines and price tests for each of the categories. There are also price tests for existing medicines.

The expected result of this program activity is that prices charged by patentees for patented medicines sold in Canada are not excessive according to the factors set out in the *Patent Act*.

The indicator that shows the PMPRB is achieving its expected results and thus its strategic outcome is the percentage of patented medicines that are within the Guidelines.

The program activity supports the Government of Canada's Social Affairs outcome of Healthy Canadians by ensuring that Canadians have access to patented pharmaceutical products at prices that are not excessive.

Program Activity 2: Pharmaceutical trends

Financial Resources ($ thousands)

2008-2009	2009-2010	2010-2011
2,648.0	2,648.0	2,648.0

Human Resources

2008-2009	2009-2010	2010-2011
20.5	20.5	20.5

The PMPRB is also responsible for ensuring that Canadians are informed about pharmaceutical trends. Within this program activity, the PMPRB has the responsibility to report annually on the PMPRB's major activities, on analyses of pharmaceutical prices and price trends, and on research and development expenditures as reported by pharmaceutical patentees.

Patentees are required, under the Regulations, to report their total sales of drugs in Canada, both patented and non-patented, to the PMPRB. Patentees are also required to submit detailed price or revenue and volume information, by class of customer[6] in each province and territory, for patented drugs sold in Canada. This information allows the PMPRB to analyze trends in sales, utilization and prices among patented drugs. Results of this analysis are presented in the PMPRB's Annual Report.

The PMPRB maintains the Patented Medicine Price Index (PMPI) to monitor trends in prices of patented medicines sold in Canada based on the Average Price across Canada. It is updated annually using price and sales information reported by patentees.

In accordance with the *Patent Act*, and the Regulations, patentees must also report all publicly available ex-factory prices of patented drugs in seven foreign countries: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. The PMPRB uses this information to: 1) conduct the international price comparison tests specified in the Guidelines; and 2) compare the Canadian prices of patented drugs to those in other countries. The PMPRB uses this information to report on price changes by country.

Under the *Patent Act*, the PMPRB monitors and reports on R&D spending in Canada, but has no regulatory authority over the amount or type of research spending by patentees.

Another responsibility pertains to the Minister's direction to the PMPRB, under section 90 of the *Patent Act*, to play a role in the National Prescription Drug Utilization Information System (NPDUIS). This initiative involves preparing critical analyses of prescription drugs so that Canada's health system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost increases. The Canadian Institute for Health

[6] Class of customer: pharmacies, hospitals, wholesalers, others.

Information (CIHI) and the PMPRB are partners in the NPDUIS. A steering committee, comprised of representatives of F/P/T public drug plans (excluding Quebec) and Health Canada, advises the PMPRB on the development of NPDUIS priorities for analytical studies.

In 2008-2009, the PMPRB will produce a Price Trends Overview Report. It is intended that this report will be generated every other year. This report provides information on drug price and expenditure trends, price levels and cost drivers facing provincial/territorial drug plans.

In addition, the PMPRB will focus on studies that will involve the development of methodologies that can be used on an ongoing basis to address areas of concern for public drug plans and selected studies based on the priorities of public drug plans.

In 2007-2008, the PMPRB produced a *New Drug Pipeline Monitor* report. This will become a standard report published annually. The report summarizes information on new drugs that are in the later phases of research and could have a significant impact in terms of therapeutic value. Other studies include an Expenditures Forecast Methodology (in progress) and assistance to the F/P/T National Pharmaceuticals Strategy on the costing of catastrophic drug coverage.

Finally, the PMPRB reports on non-patented prescription drug prices. In the fall of 2005, F/P/T Health Ministers agreed that the PMPRB be asked to monitor and report on non-patented prescription drug prices. This is in support of the F/P/T and the National Pharmaceutical Strategy priority to achieve potential parity in non-patented prescription drug prices (NPPDP).

Funding for both of these initiatives (NPDUIS and NPPDP) was provided through reallocation of funds from Health Canada's budget.

As a result of a new Memorandum of Agreement with Health Canada, for 2008-2009 and beyond, studies under NPDUIS and on NPPDP will be merged under NPDUIS due to a reduction in funding for NPDUIS and the fact that Health Canada will no longer provide its own direct funding for data from IMS Health to support NPPDP. Instead, as a result of a Data Sharing Agreement between the PMPRB and the CIHI, the PMPRB will primarily use class level prescription drug information from participating F/P/T drug plans to carry out NPDUIS studies and, as resources permit, analyses of provincial drug prices and trends on non-patented prescription drugs.

The expected result of this program activity is that stakeholders are more aware of pharmaceutical trends and cost drivers. This information contributes to informed decisions and policy-making.

The indicators that show that the PMPRB is achieving this expected result are: 1) the number of requests for PMPRB publications; and 2) the number of events where the PMPRB participates.

This program activity supports the Government of Canada's Social Affairs outcome of Healthy Canadians by ensuring that Canadians are more aware of pharmaceutical trends and cost drivers.

SECTION III – SUPPLEMENTARY INFORMATION

Table 1: Departmental links to the Government of Canada Outcomes

Strategic Outcome: Canadians and their health care system are protected from excessive pricing for patented medicines sold in Canada and are informed on pharmaceutical trends.					
		Planned Spending ($ thousands)			**Alignment to Government of Canada**
Program Activity	**Expected Results**	**2008-2009**	**2009-2010**	**2010-2011**	**Outcome Area**
Compliance and enforcement of non-excessive pricing for patented medicines	Prices charged by patentees for patented medicines in Canada are not excessive according to the factors of the *Patent Act*.	3,194.0	3,194.0	3,194.0	Healthy Canadians
Pharmaceutical trends	Stakeholders are more aware of pharmaceutical trends and cost drivers.	2,648.0	2,648.0	2,648.0	Healthy Canadians

Tables available electronically at: http://www.tbs-sct.gc.ca/est-pre/20082009/p3a_e.asp

Table 2: Services Received Without Charge

Table 3: Sources of Non-respendable Revenue